K081415

SYBRON DENTAL SPECIALTIES

SEP 2 4 2008

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7602 - Phone
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Wendy Garman - Contact Person

Date Summary Prepared: May 2008

Device Name:

- Trade Name - Damon 4Clear
- Common Name – Bracket, Ceramic, Orthodontic
- Classification Name – Bracket, Plastic, Orthodontic, per 21 CFR § 872.5470

Devices for Which Substantial Equivalence is Claimed:

- Ormco Corporation, *Lumina*
- Dentsply International, *In-Ovation C*
- 3M Unitek Corporation, *Clarity Modified Ceramic Bracket*

Device Description:

The device is a ceramic orthodontic bracket which will encompass maxillary and mandibular brackets from 2nd bicuspid to 2nd bicuspid. The *Damon 4Clear* appliance has both aesthetic and self-ligating qualities. The *Damon 4Clear* is designed with 1) improved open and close functionality and increased corner radius for increased patient comfort, 2) enhanced bracket placement with placement jigs and 3) improved overall bracket performance without changing treatment mechanics, with rotation and torque control similar to other Damon metal brackets. This system is a bondable device for fixed attached orthodontics.

Intended Use of the Device:

The *Damon 4Clear* is a ceramic bracket system intended to aid in the movement of patient teeth during orthodontic treatment.

Substantial Equivalence:

Damon 4Clear is substantially equivalent to other legally marketed devices in the United States. *Damon 4Clear* functions in a manner similar to and is intended for the same use as the *In-Ovation C* bracket marketed by Dentsply International, the *Clarity Modified Ceramic Bracket* marketed by 3M Unitek Corporation and the *Lumina* bracket formerly marketed by Ormco Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 4 2008

Ormco Corporation
C/o Ms. Wendy Garman
Director, Regulatory Affairs
Sybron Dental Specialist, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K081415
Trade/Device Name: Damon 4Clear
Regulation Number: 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NJM
Dated: August 14, 2008
Received: September 10, 2008

Dear Ms. Garman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Samuel Lin for

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081415

Device Name: *Damon 4Clear*

Indications For Use:

The Damon 4Clear is a ceramic bracket system intended to aid in the movement of patient teeth during orthodontic treatment.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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